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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,030	06/29/2001	J. Norman Hansen	108172-00058	5493

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 12/26/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/894,030

Applicant(s)

HANSEN, J. NORMAN

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 9-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in Paper No. 6 is acknowledged.

Claims 9-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Information Disclosure Statement

The listing of references in the specification (pages 17-18) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A (1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892 or by Applicants on PTO-1449, they have not been considered.

Reference AA has been crossed out as it is not a publication. It is noted that this application claims priority from the provisional application; such documents are reviewed to determine effective filing dates.

Applicant is requested to supply additional publication information for reference AM, specifically the year of publication. All other missing publication information was present on the first page of the reference, and was added to the PTO-1449 by the Examiner.

Specification

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The disclosure is objected to because of the following informalities: page 1, section 0002, line 2 recites an application number. Only patent publications can be incorporated by reference.

Appropriate correction is required.

Claim 16 is objected to because of the following informalities: "of" is missing between "1-37" and "SEQ".

. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 , 15 and ~~18~~ 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a sublancin peptide comprising residues 1-37 of SEQ ID NO: 2, and a method of decontaminating gram-positive bacterial spores, does not reasonably provide enablement for any sublancin peptide or the activity of the peptide against any bacteria. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A name of a protein in the absence of sufficient structural information (i.e., SEQ ID NO.) or functional characteristics does not serve to identify the claimed invention.. It noted that the name of a protein or peptide can change over time, as more becomes known about the protein, e.g. the

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alternate known names for interleukin 1 (Callard). The only example of a sublancin is that of sublancin 168, which is SEQ ID NO:2.

With respect to claims 20-21, it is noted that PAIK *et al.* showed no activity of sublancin 168 against Gram-negative bacteria. Further, the specification offers no information to counter this finding.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. It is acknowledged that Applicant has shown activity of the sublancin peptide against a wide variety of gram-positive bacteria & thus has description for the generic claims ; however, it is noted that claim 22 is directed to decontaminating a *Bacillus anthracis* spore containing area . The technical difficulty of decontaminating an environment contaminated with such spores is widely known in the art (see, e.g., the discussions by Ingelsby *et al.* pages 2249-2250, and by Hawley *et al.*, pages 243-245). For this reason, it is deemed that the disclosure of the specification is insufficient to describe a method of decontaminating a *Bacillus anthracis* spore containing area. Evidence of successful decontamination of these specific spores could overcome this rejection.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. What is not described in cannot be considered enabled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over PAIK *et al.* in view of OLSEN *et al.* (US patent 6143498). The PAIK *et al.* reference teaches the production of the antimicrobial peptide sublancin-168 and the activity of the peptide against a variety of different bacteria that are either Gram positive or negative; it does not teach the addition of a his-tag to that peptide for simple purification. Olsen *et al.* teach the addition of a his-tag to an antimicrobial peptide in order to facilitate purification, but are silent on sublancin. They state in Example 1 that a specific commercially available expression vector contains six codons for histidine and that the elements of the vector are so arranged that the histidine residues are attached to the carboxy end of an expressed polypeptide. It is noted that their construct is such (see column 20, lines 48-65) that several codons are placed between the his codons and the carboxyl end of the peptide; thus their expressed his-tag polypeptide contains a spacer between the carboxyl end of their peptide and the his codons. One of ordinary skill in the art at the time of the invention would have expected to utilize the same system as Olsen *et al.* in order to obtain other His-Tag antimicrobial peptides, such as the sublancin 168 of PAIK *et al.*, with a reasonable expectation of success. The Examiner notes that the specification states on page 6, lines 17-22 that attempts to affinity label other antibiotics were unsuccessful;

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however, no other information is presented. The Examiner notes that epidermin has been affinity labeled with a his tag (KUPKE *et al*).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 15-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 11-14, and 30 of copending Application No. 09/462478 in view of OLSEN *et al.* (US patent 6143498).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

The claims of the copending application are to peptides having a specific degree of sequence similarity with SEQ ID NO:7 (sublancin 168, and a method of inhibiting spore outgrowth of gram positive bacteria, whereas the instant claims are directed to sublancin-168 with a his tag

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and to a method of decontaminating a spore infected are with the tagged peptide. Olsen *et al.* is discussed above. In light of the histidine tagged antimicrobial peptides of Olsen *et al.*, the instant claimed his tag sublancin 168 peptides are an obvious variation of the allowed claims of the copending application, as is their use in killing bacterial spores.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed

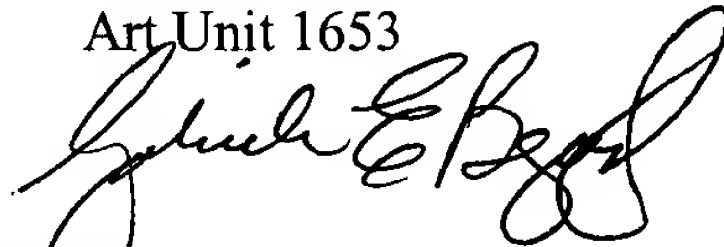
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. KUPKE *et al.* show production of the lantibiotic epidermin with a His tag, thereby permitting affinity purification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
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GABRIELLE BUGAISKY
PRIMARY EXAMINER

December 20, 2002